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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09 648,864 | 08/25/2000 | Howard M Johnson | UF-243X | 6790 |

23557 7590 10/21/2002

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EXAMINER

ANDRES, JANET L

ART UNIT PAPER NUMBER

1646

DATE MAILED: 10/21/2002 14

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/648,864

Applicant(s)

JOHNSON ET AL.

Examiner

Janet L Andres

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 July 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 25, 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25, 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s) _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

RESPONSE TO AMENDMENT

1. Applicant's amendment filed 10 July 2002 is acknowledged. Claims 25 and 30-39 are pending in this application. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior office action.

Claim Rejections Withdrawn

2. The rejections of claims 25-39 under 35 U.S.C. 112, first paragraph, are withdrawn in response to Applicant's arguments.

3. The rejection of claims 26-32 and 36 under 35 U.S.C. 112, second paragraph, is withdrawn in response to Applicant's amendment.

4. The rejection of claims 35, 36, and 33-39 under 35 U.S.C. 102(b) is withdrawn in response to Applicant's amendment.

Claim Rejections Maintained

5. The rejection of claims 30-39 under 35 U.S.C. 103(a) is maintained for reasons of record in the office action of paper no. 10 and newly applied to claim 25.

Applicant argues that one of ordinary skill in the art would not expect interferon tau to have the same properties as interferon alpha, even though it binds to the same receptor. Applicant points to the teachings of Subramaniam et al. as indicating that interferon tau recognizes the receptor differently and has different activities, and concludes that one of ordinary skill could not extrapolate from other interferons to interferon tau.

Applicant's arguments have been fully considered but have not been found to be persuasive. Subramaniam et al. teaches that a subspecies of interferon alpha binds the receptor with higher affinity than interferon tau, and teaches that this difference may be responsible for

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the higher toxicity of interferon alpha. However, Subramanian et al. teaches that the antiproliferative and antiviral properties of interferon alpha and interferon tau are very similar, as is the ability to induce 2'5'-oligoadenylate synthetase activity (p. 12270). Subramanian et al. further teaches that the ability of interferon tau to activate signal transduction molecules associated with interferon signaling is very similar to that of interferon alpha, and concludes that cytotoxicity, unlike antiviral and antiproliferative activity, occurs only at high levels of receptor occupancy. Thus, one of ordinary skill in the art would have expected interferon tau to function as well as interferon alpha, because, like WO 97/39127, Subramanian et al. teaches that its therapeutic properties are very similar. One of ordinary skill would recognize that cytotoxic effects are distinct from the therapeutic effects of interferon alpha, because Subramanian et al. teaches that they require much higher levels of receptor occupancy and are not correlated with the activation of signal transduction systems (p. 12274). That Subramanian et al, like WO 97/39127, teaches that interferon tau is less toxic would provide additional motivation for one of ordinary skill in the art to use it in place of interferon alpha.

NO CLAIM IS ALLOWED.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this group is (703) 872-9306 or (703) 872-9307 for after final communications.


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Communications via internet mail regarding this application, other than those under U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet Andres, Ph.D.
October 17, 2002


YVONNE EYLER, Ph.D.
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600